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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,691	09/05/2001	Angus George Dalgleish	37945-0018	6462

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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,691	DALGLEISH ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

It is noted that the claims of the instant application have been determined to include linking claim 1. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims directed to the following patentably distinct inventions linked by claim 1:

Groups 1-3,628,800. Claims 1-10, 13-20, drawn to an allogeneic immunotherapeutic agent comprising three human prostate cell lines from three different sources of cell lines derived from non-cancerous prostate tissues or tumor tissues, of which one, two or all three cell lines are derived from normal non-cancerous prostate tissues, wherein the cell lines derived from normal tissue are PNT1A or PNT2,

and the cell lines derived from cancer tissue are NIH1519-CPTX, NIH1532-CP2TX, NIH1535-CP1TX, NIH1542-CP3TX, CA-HVP-10, LnCap, DU145 or PC3, classified in class 424, subclass 93.7. It is noted that the number of possible combination of the cell lines was determined by a factorial calculation, that is 10 factorial or 3,628,800 possible combinations. Each combination of any of the three above cell lines constitutes a single invention.

Groups 3,628,801-7,247,600. Claims 1, 11-12, drawn to an allogeneic immunotherapeutic agent comprising a vaccine adjuvant and three human prostate cell lines from three different sources of cell lines derived from non-cancerous prostate tissues or tumor tissues, of which one, two or all three cell lines are derived from normal non-cancerous prostate tissues, wherein the cell lines derived from normal tissue are PNT1A or PNT2, and the cell lines derived from cancer tissue are NIH1519-CPTX, NIH1532-CP2TX, NIH1535-CP1TX, NIH1542-CP3TX, CA-HVP-10, LnCap, DU145 or PC3, classified in class 424, subclass 93.7. It is noted that the number of possible combination of the cell lines was determined by a factorial calculation, that is 10 factorial or 3,628,800 possible combinations. Each combination of any of the three above cell lines constitutes a single invention.

Groups 7,247,601-10,876,400. Claims 21-22, drawn to a method of preventing prostate cancer, by administering an allogeneic immunotherapeutic agent comprising three human prostate cell lines from three different sources of cell lines derived from non-cancerous prostate tissues or tumor tissues, of which one, two or all three cell lines are derived from normal non-cancerous prostate tissues, wherein the cell lines derived

from normal tissue are PNT1A or PNT2, and the cell lines derived from cancer tissue are NIH1519-CPTX, NIH1532-CP2TX, NIH1535-CP1TX, NIH1542-CP3TX, CA-HVP-10, LnCap, DU145 or PC3, classified in class 424, subclass 93.7. It is noted that the number of possible combination of the cell lines was determined by a factorial calculation, that is 10 factorial or 3,628,800 possible combinations. A method using each combination of any of the three above cell lines constitutes a single invention.

Groups 10,876,401-14,505,200. Claims 21-22, drawn to a method of treating prostate cancer, by administering an allogeneic immunotherapeutic agent comprising three human prostate cell lines from three different sources of cell lines derived from non-cancerous prostate tissues or tumor tissues, of which one, two or all three cell lines are derived from normal non-cancerous prostate tissues, wherein the cell lines derived from normal tissue are PNT1A or PNT2, and the cell lines derived from cancer tissue are NIH1519-CPTX, NIH1532-CP2TX, NIH1535-CP1TX, NIH1542-CP3TX, CA-HVP-10, LnCap, DU145 or PC3, classified in class 424, subclass 93.7. It is noted that the number of possible combination of the cell lines was determined by a factorial calculation, that is 10 factorial or 3,628,800 possible combinations. A method using each combination of any of the three above cell lines constitutes a single invention.

In addition, upon election of any of groups 1-14,505,200, further election of the following patentably distinct species is required:

Activation of immune T cells, or induction of antibody production, or induction of a decrease in the rate of rise in the level of serum PSA in prostate cancer patients, or induction of a decline in the level of serum PSA in prostate cancer patients.

Upon election of any of groups 3,628,801-7,247,600, further election of the following patentably distinct species is required:

Any one of the adjuvants recited in claims 11 and 12.

The inventions are distinct, each from each other because of the following reasons:

Inventions (1-7,247,600) and (7,247,601-14,505,200) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a cell line could be use for several purposes, for example, for testing drugs, for assays, and for treating diseases.

The products of groups 1-7,247,600 are patentably distinct, because they are drawn to a combination of different cell lines with different properties.

The products of groups 1-3,628,800 are distinct from the products of groups 3,628,801-7,247,600, because the product of groups 3,628,801-7,247,600 contain additional compositions, i.e. vaccine adjuvants, not found in groups 1-7,247,600.

The methods of groups 7,247,601-14,505,200 are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species adjuvants are distinct because they have different structure, characteristics and properties.

The species of the immune response are distinct because they have different characteristics and properties.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

January, 06, 2002

SUSAN UNGAR, PH.D
PRIMARY EXAMINER